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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/063,356	04/21/98	BEATTIE K	029623/0109

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COLIN G. SANDERCOCK
FOLEY & LARDNER
3000 K ST NW
STE 500
WASHINGTON DC 20007-5109

EXAMINER	
SAUNDERS, D	
ART UNIT	**PAPER NUMBER**
1644	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
063,356	BEATTIE
Examiner	**Group Art Unit**
SAUNDERS	1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 21-82 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 21-22, 25-32, 34-82 is/are rejected.

☑ Claim(s) 24, 33 is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

Part of Paper No. _____

The amendment filed on 8/28/98 has been entered. Applicant is reminded that the proper Serial No. is 09/063,356, not 08/631,751. Claims 21-82 are pending and under examination.

The abstract is objected to. It is not clear what is meant by "allowed" at line 6.

The disclosure is objected to because of the following informalities:

The insert of continuation data at page 1, via a preliminary amendment filed 4/21/98, has not updated the current status of each U.S. application recited.

Appropriate correction is required.

Claims 27-32, 34-37, and 40-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims contain new matter as follows.

Claim 27 contains new matter by reciting "about 0.33 micrometers to about 10 micrometers" col. 9, line 51 of Pat. 5,843,767 recites "33 nm" (0.033 micrometer) without "about". Further, "10-micron diameter" (col. 9, line 4) does

not support "about 10". Note, for convenience, the examiner will refer to the specification of issued Pat. 5,843,767 which has the same specification as the instant application.

Claim 28 contains new matter by reciting "about 0.45 micrometers to about 10 micrometers". Col. 10, line 18 of '767 recites 450nm (0.45 micrometer) without "about". As noted supra with respect to claim 27, there is no support for "about 10".

In claims 29, 50 and 72 it is not clear what specific diameters support the recited cross-sectional areas. Also, it is not clear that recitation of "about" are supported.

In claim 30 "about 100 um to about 1000 um" is not supported, col. 10, line 12 does not recite "about".

In claims 31, 51 and 73 it is not clear what disclosed channel diameters and lengths have resulted in the calculated inner surface areas, and it is not clear that recitations of "about" are supported.

areas not supported since, area can be same with a plurality of diameters and lengths

For claims 32, 52 and 74 it is not clear what disclosed dimensions in Example 7 have given rise to the recited group areas, nor has support for recitations of "about" been shown.

With respect to claims 34, 54 and 76 it is not clear what disclosed dimensions support the recited ratio of areas. Also, it is not clear where there is support for recitations of "about".

For claims 37, 55 and 77 it is not clear where there is support for a generic "label", other than the specific labels disclosed in Example 9.

In claims 35, 45 and 67 it is not clear where there is support for "glass or silicon" other than "nanoporous glass" (col. 5, line 53) or "porous silicon" (col. 11, line 55).

In claim 44, part A) it is not clear where the first and second binding reagents for detecting expression of a gene are supported. Given the recitation at col. 8, line 59 it appears that these should be recited as "gene-specific probes", of which Example 11 specifically exemplified various cDNA clones. Different cDNA clones where applied to different groups of channels (col. 22, lines 1-19); thus, there is no support for the assay of claim 44 without the limitations of claims 48-

49. Further, a gene specific probe would at the least require the limitation of "hybridization" in claim 61.

It is not clear where there is support for "RNA" in claim 59, since Example 11 disclosed only cDNA.

For like reason, "polynucleotides" in claim 60 is overly broad.

There is no clear support for "different conditions" in claim 63, since col. 22, line 64 has recited "different culture conditions".

Support for claim 64 cannot be found in Example 11. Applicant cannot point to Example 10, since that example is directed to mutation detection, rather than to profiling gene expression.

In claim 55 (66) part (A) it is not clear where there is support for a generic "first binding reagent" and a generic "second binding reagent" for use in a method to detect "sequence variation". This was disclosed as involving DNA as the binding reagent (e.g. col. 7, line 58 - col. 8, line 54). Figure 5 and Example 10 referred to by applicant for support, also only show DNA as the binding reagent. It is further not clear as to how any method other than "hybridization", recited in claim 80,

would be supported. It is further not clear where use of RNA or cDNA, recited in claim 81, would be supported by the above portions of the disclosure.

Furthermore, since Figure 5 and Example 10 show different oligonuclotide binding reagents bound to different groups of channels, it is not clear where there is support for the method of claim 66 without the limitation of claim 70.

Claims 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 38 "said detectable label" lacks antecedent basis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at

the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1st Art rejection

Claims 21, 25-30, 34, 37-44, 50-51, 54-60, 66, 72, 76-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Degen et al. (4,693,985) in view of Chandler (4,874,691) and as necessary Brown III et al. (4,916,056).

Degen et al. disclose polyamide membranes that characterized by having through pores extending from surface to surface which are of substantially uniform size and shape. See col. 6, lines 7-11. Pore diameters are about 0.1 to about 1.2 microns (col. 7, lines 26-29). The filter of Degen et al. has immobilized biologically active acceptor molecules and can be used in immunoassays. See col. 3, lines 22-66 and col. 13, lines 25-29. The surface for immobilization includes the surfaces which defines the pores of the membrane. See col. 5, lines 34-45. The filters of Degen et al. thus have all of the characteristics of the substrate recited in instant claim 1.

Degen et al. do not disclose the steps of immunoassays that are contemplated in detail. It is, however, clear from their disclosure that labeled materials bound by ligand/receptor interactions can be detected when bound to the membrane. See

Example 12 showing detection of 125I labeled goat anti-rabbit IgG bound to immobilized rabbit IgG. Similarly, note Examples 14-15.

Chandler shows immunoassay steps that are well known in the art and how to conduct immunoassays on a membrane, with reading of the amount of captured analyte via detection of label bound to the membrane. Note, for example, the sandwich assay in Example 1. Thus, Chandler shows the steps by which one of ordinary skill would have expected to be able to conduct the immunoassays that Degen et al. teach can be conducted using their own membranes. The amount of analyte, or target substance in a sample that binds to the biologically active acceptor molecules (instant binding reagent) is thus detected within the substrate as required by step B) of instant claim 21.

The above stated rejection is deemed proper since there is nothing to distinguish the instant "first binding reagent immobilized on... a first group of channels" from the instant "second binding reagent immobilized on a second group of channels" in claim 21, part A). In fact, applicant contemplated the first and second binding reagents being the same; otherwise, applicant would not have recited claim 25. With the first and second binding reagents being the same, the

filters of Degen et al. prepared to test for one analyte would clearly be the same as applicant's.

With respect to the case in which the first and second binding reagents are different. It is noted further that Figure 8 of Chandler, shows development of color from an enzyme label in the form of a plus sign. While the disclosure relates no more, it is well known in the art that plus signs can be constructed such that there are two different binding reagents in different portions of the plus sign. See, for example, Brown III et al. at col. 11, lines 18-37 showing the different binding reagents that are provided within the different portions of a plus sign. When providing reagents for such plus signs on the filter membranes of Degen et al., these would be no different from the filter device used in the method of instant claims 25-26, that is, the "first binding reagent" and the "second binding reagent" would be immobilized on different portions of the substrate.

With respect to dependent claims reciting dimensions note the following teachings of Degan et al.

Degen et al. teach (col. 7, lines 26-29) pore diameters of 0.1 to 1.2 microns, which overlaps the ranges recited in instant claims 27-28.

The above diameters convert to pore cross-sectional areas of 7.9 X 10 to the minus 3 and 1.1 square microns, respectively. These are well within the range recited in instant claim 29.

Degen et al. teach (col. 14, lines 46-51 membranes having a thickness of 5-6 mils (i.e. 0.005 to 0.006 inches). In instant claim 30, "about 100um" converts to "about 0.0039 inches", which is reasonably considered to encompass 0.005-0.006 inches of the reference.

should have also rejected claim 31, 51, 73 see CIP 213,932 re claim 7

Degen et al. teach that membranes can be constructed that have a total surface membrane area of 650 square meters in a membrane having an outer membrane area of 9 square feet. See col. 14, lines 49-53. See col. 5, lines 27-48 for definitions of surface area. Assuming 9 square feet is approximately one square meter, The disclosure of Degen et al. is well within the range of ratios in instant claim 34.

where to look up 213,932

With respect to claims 37-38, Degen et al. and the secondary references show the recited labels.

Claim 39 is rejected, since in competitive binding immunoassays, there is competition between the target substance (analyte) and a labeled form thereof.

Claims 40-43 are rejected because it is well known that various types of ligands and receptors other than antigens/antibodies can participate in binding reactions like those involved in immunoassays. See Degen et al. at col. 11, lines 3-24. See Brown III et al. in the abstract.

With respect to claims 44, 66 and their dependents, it is well known in the art that a mutant sequence or the expression of a nucleic acid can be detected via nucleic acid hybridization methods similar to those employed in immunoassays -- e.g. competitive binding or sandwich assays could detect a nucleic acid target species expressed by a pathogen or could detect a mutant oncogene.

Claims 23-24, 35-36, 45-46, 67-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Degen et al., in view of Chandler and Brown III et al. as

applied to claims 21, 25-30, 34 and 37-43 are above, and further in view of Tonucci et al. (5,234,594 cited on 1449).

Tonucci et al. teach the further aspect that nanochannel glass filters may be used for molecular absorptions/chromatographic separations and biological separations. See col. 6, line 24 - col. 7, line 10. Degen et al. have taught that their porous membranes may be used for like purposes, as well as for immunoassays. Thus, the membranes of Degen et al., and the glass filters of Tonucci et al. are considered functional equivalents, and it would have been obvious to use the glass filters of Tonnucci et al. in the immunoassays, as taught by Degen et al.

Patent 5,677,195 is cited as of interest. It shows a test device having channels; however, these are not pores that connect two major surfaces of a substrate.

On attached from 1449, foreign Pat. documents that are not in English have not been considered. Journal reference A24 has not been considered, since it was not submitted with the papers filed 4/26/98 and could not be found in the file of grandparent 141,969.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner D. Saunders, whose telephone number is (703) 308-3970. The examiner can normally be reached on Monday through Friday from 8:15 AM to 4:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1674

SAUNDERS; aco

May 19, 1999